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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,086	11/29/1999	PASCUAL PEREZ	BET-99/0730	2155

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ARLINGTON, VA 22202

EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/380,086

Applicant(s)

PEREZ ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29 and 37-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

1. Claims 29 and 37-39 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of claims 29-30 and 33-34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's amendment of the claims.
4. The rejection of claims 29-30 and 33-34 under 35 U.S.C. 103(a) as being unpatentable over D'Halluin et al (US Patent 5,712,135, filed June, 1995) in view of Metz et al (1995, Mol. Breed. 1:309-317) and Lenée et al (US 6,573,431, filed April 1996) is withdrawn in light of Applicant's amendment of the claims.
5. The abstract is not descriptive of the instant invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.
6. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

### ***Claim Rejections - 35 USC § 112***

7. Claims 29 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for preventing dissemination of a transgene

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encoding dog gastric lipase or collagen, wherein the transgene is on the same vector as a gene conferring male sterility and wherein the gene conferring male sterility and the transgene encoding dog gastric lipase or collagen are each operatively linked to a transcriptional control system, does not reasonably provide enablement for a method for preventing dissemination of a transgene encoding dog gastric lipase or collagen, wherein the transgene is on the same vector as a gene conferring male sterility and wherein the gene conferring male sterility and the transgene encoding dog gastric lipase or collagen are operatively linked to the same transcriptional control system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is different from the rejection set forth in the Office action mailed 30 November 2004, as applied to claims 29-30 and 33-34. Applicant's arguments filed 31 May 2005 have been fully considered but do not address the issues in this new rejection.

The claims are broadly drawn to methods for preventing dissemination of a transgene encoding dog gastric lipase or collagen, wherein the transgene is on the same vector as a gene conferring male sterility and wherein the gene conferring male sterility and the transgene encoding dog gastric lipase or collagen are operatively linked to the same transcriptional control system or are each operatively linked to a transcriptional control system.

The instant specification, however, only provides guidance for construction of plant transformation vectors comprising a gene conferring male sterility, comprising the A9 promoter operably linked to either the glucanase or the barnase gene, a gene encoding dog gastric lipase, and a gene conferring resistance to Basta (examples 1-2); and transformation of the vectors into *Brassica napus* (example 3) and tobacco (example 4). The instant specification also provides

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guidance for construction of a plant transformation vectors comprising the Ac transposase gene (example 5) and one presumably comprising the A9 promoter operably linked to the glucanase gene and excision sequences (example 6); transformation of the vector of examples 5 and 6 into separate tomato plants (example 7); constructing a vector comprising a Ds element inserted into the Gus gene, transforming this into plants and showing that the plants produced blue spots, *i.e.*, that the Ds element was excised (example 8); and generation of T2 seeds that contain an unidentified transgene (example 9). The instant specification also provides guidance for crossing male sterile plants containing the Ds element and an unknown artificial male sterility gene to plants expressing the Ac transposase (example 10); identification of the excision event in F1 plants by PCR to determine which no longer have the AMS gene - such plants in an unexplained manner also lack the transposase gene but have an undefined gene of interest (example 11); and construction of a plant transformation vectors containing the FLP recombinase (example 12) and the one containing a A9-barnase male sterility gene and a kanamycin resistance gene between FRT recombination sites (example 13).

It is noted that following what exactly was done in the examples and what each vector and plant comprises is very difficult, and in some cases impossible, to determine from the specification.

The claimed method requires that the transgene be incorporated into the nuclear genome, that the transgene encoding dog gastric lipase or collagen be prevented from dissemination in the pollen of the plant, and that the dog gastric lipase or collagen be isolated from the plant. Thus, expression of both the transgene and the gene conferring male sterility must be expressed.

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However, in nuclear gene expression, two open reading frames cannot be expressed from the same transcriptional control system; each open reading frame must have its own system.

The specification does not teach how to overcome this inherent feature of eukaryotic transcription. Thus, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for preventing dissemination of a transgene encoding dog gastric lipase or collagen, wherein the transgene is on the same vector as a gene conferring male sterility and wherein the gene conferring male sterility and the transgene encoding dog gastric lipase or collagen are operatively linked to the same transcriptional control system.

8. Claims 29 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is different from the rejection set forth in the Office action mailed 30 November 2004, as applied to claims 29-30 and 33-36. Applicant's arguments filed 31 May 2005 have been fully considered but do not address the issues in this new rejection.

Claim 29 lacks antecedent basis for the limitation "the dog gastric lipase or collagen" in lines 12-13.

Claim 39 lacks antecedent basis for the limitation "the promoter".

### *Conclusion*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

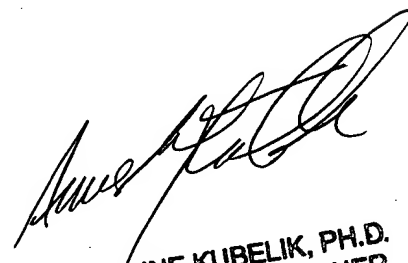
The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.  
August 16, 2005



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER